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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,817	10/29/2003	Eyal Raz	UCAL-292	1602

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EXAMINER	
HORNING, MICHELLE S	
ART UNIT	**PAPER NUMBER**
1648	

MAIL DATE	DELIVERY MODE
07/25/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/697,817	RAZ ET AL.	
	Examiner	Art Unit	
	Michelle Horning	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 5/4/2007.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-26 is/are pending in the application.

4a) Of the above claim(s) 10-11, 15, 18-23 is/are withdrawn from consideration.

5)☒ Claim(s) 3-5, 14, 16-17 is/are allowed.

6)☒ Claim(s) 1,2,6-9,12,13 and 24-26 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 29 October 2003 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is responsive to communication filed 5/4/2007. The status of the claims is as follows: claims 1-17 and 24-26 are under current examination and claims 18-23 are withdrawn from consideration because they are drawn to non-elected inventions. Because the examined inventions appear to be free of the art, the full scope of the claims were examined.

The following objections and rejections have been withdrawn to claim amendments or persuasive arguments:

1. Claim objection (claim 7);

2. Claim objections (claims 2 and 5-9);

3. 35 USC 102(e);

4. 35 USC 102(b); and

4. 35 USC 103(a);

Double Patenting-MAINTAINED

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-2, 6-9, 12-13 and 24-26 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 and 15 of U.S. Patent No. 6, 498, 148. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method steps from both sets of claims involve the same population of individuals and the same product being administered, thus resulting with the same inherent effect.

In response, Applicants state that the '148 patent is directed to treating asthma, in contrast to the instant application which is drawn to a method of treating airway remodeling. Thus, Applicants state that they are patentably distinct from each other.

Although nebulous and without any detail, Applicants' argument is considered but not found persuasive. Paragraph 41 of the instant application specifically discloses that airway remodeling is associated with chronic asthma (see under Pathological Parameters). Further, the instant specification recites the following: " The instant invention provides methods of treating airway remodeling that is associated with chronic asthma" (paragraph 41). Thus, while they differ in their scope, both sets of claims have similar method steps drawn to comparable populations of individuals. Further, the claims are drawn to treating individuals that are suffering specifically from asthma; this rejection is maintained.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-17 and 24-26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for some sequences containing CpG, does not reasonably provide enablement for all TLR agonists. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make/use the invention commensurate in scope with these claims. Enablement is considered in view of the *Wands* factors.

Nature of the invention. The claims are drawn to a method for treating airway remodeling suffering from chronic asthma using all possible TLR agonists or CpG-containing sequences.

State of the prior art. It is known that CpG oligodeoxynucleotides in acute models can successfully modulate airway inflammation (see Kline et al, 1998). Of note, the Applicant has failed to show how there would be different results in the acute model than from the chronic model found in the instant application.

Breadth of the claims. The claims are not limited to any specific TLR agonist or CpG containing sequences.

Working examples. The examples do not show that all CpG sequences can be used to treat chronic asthma wherein airway remodeling is reduced.

Guidance in the specification. The specification provides little to no guidance regarding the full scope of the methods as claimed. No guidance is provided in determining which CpG sequences should be used for the successful practice of the claimed methods.

Predictability of the art. The physiological art in general is acknowledged to be unpredictable (MPEP 2164.03). In the instant application, Applicant has not provided any common structure (e.g. motifs) that would lead the function as claimed (treating chronic asthma, reducing airway remodeling). No one could predict which structures of the CpG sequences that would lead to this function.

Amount of experimentation necessary. It would require much experimentation to ascertain both the structure and function of the CpG sequences that would lead to the successful practice of the claimed methods. Much work is left for others to do.

For the reasons discussed above, it would require undue experimentation for one skilled in the art to make and use the full scope of the methods.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michelle Horning whose telephone number is 571-272-9036. The examiner can normally be reached on Monday-Friday 8:00-5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michelle Horning

JEFFREY S. PARKIN, PH.D.
PRIMARY EXAMINER